



This lot of product meets the accepted performance criteria recommended in the USP and ISO 11138-1, ISO 11138-2, ISO 11138-3 and ISO 11138-4.

Product Name: Growth Medium

For Use with: *Geobacillus stearothermophilus*, *Bacillus atrophaeus*, *Bacillus subtilis*, or *Bacillus pumilus*

<b>LOT</b>	010121-01	<b>REF</b>	SGM-100	Quantity:	100 Tubes
	2021-01-01		2022-07-01 (YYYY-MM-DD)		

**Instruction for Use**

After exposure to the sterilization process, aseptically transfer each carrier to an individual tube of the modified growth medium. Controls: A tube of growth medium containing no Inoculated Carrier may be utilized as a Negative Control. A tube of growth medium containing an Inoculated Carrier which has not been exposed to a sterilization process may be utilized as a Positive Control.

Incubate tubes containing exposed Inoculated Carriers and control tubes for a minimum of seven (7) days within the temperature range outlined in the table.

Organism	Incubation Temperature Range
<i>Bacillus atrophaeus</i> , <i>Bacillus subtilis</i> , <i>Bacillus pumilus</i>	30° - 40°C
<i>Geobacillus stearothermophilus</i>	55° - 65°C

Examine tubes for growth, daily if possible. Tubes which become turbid are positive for bacterial growth. Typical growth of *Geobacillus stearothermophilus*, *Bacillus subtilis*, *Bacillus pumilus* will display a cream-colored sediment. Typical growth of *Bacillus atrophaeus* will display an orange to cream-colored pellicle.

Result Interpretation		
Sample Type	Media remains clear, no sign of turbidity or growth	Media is turbid with visible signs of growth
Tubes Containing Test Inoculated Carrier	Effective Sterilization	Process did not kill all spores present on the BI/Inoculated Carrier
Negative Control	Test Valid	Test Invalid - indicates the growth medium was not sterile and false positives may be detected
Positive Control	Test Invalid: -the incubation temperature may not be correct -length of incubation was not sufficient -the Inoculated Carrier did not contain spores -the growth medium not capable of supporting growth	Test Valid

Storage and Shelf Life			
	Room Temperature (15° - 30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	18 Months from the date of manufacture		

Disposal: Autoclave medium tubes positive for growth, at 121°C for not less than 30 minutes. Media within processed tubes and tubes which were negative for growth may be discarded as standard waste; tubes may be recycled as glass.

\_\_\_\_\_  
QUALITY ASSURANCE APPROVAL

June 30, 2021  
DATE